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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 768,080	01.23.2001	David A. Estell	GC527C3	2502

5100 7590 06.25.2003

GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06.25.2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

768,080

Applicant(s)

ESTALC et al

Examiner

SAUNDERS

Group Art Unit

1674

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/7/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 7-10, 14-15 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 7-10, 14-15 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Amendment of 4/7/03 (paper 14) has been entered. Claims 7-10 and 14-15 are pending and under examination for the embodiment of Group I (i.e. a lessened immunogenicity), amendment has entered no new matter.

The amendment has overcome previously stated objections to the specification and claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment has obviated previously stated rejections under 35 USC 112, second paragraph.

Prior art rejections of record over Robinson et al and Rodriguez et al have been withdrawn due to applicant's amendment.

Prior art rejections of record that are maintained are stated further infra.

Claims 7-10 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claims have not been amended to encompass only the elected embodiment (a variant producing a lower immunogenic response). It is noted that applicant's response has not further traversed the restriction requirement.

The amended claims also contain Markush group members inconsistent with the elected invention. Note "vaccines" were disclosed as altered polypeptides having T-cell epitopes modified to yield a greater immunogenic response (e.g. page 10, lines 14-18).

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Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Carr et al (WO 98/52976), for reasons of record.

Carr teaches a streptokinase having substitutions within T-cell epitopes to render these less immunogenic. Applicant has urged that applicant predates Carr^{et al} by virtue of the benefit of the 4/15/98 filing date of ultimate parent application 09/060,872. This is unconvincing, since the amended version of claim 7 recites numerous Markush group members at the conclusion of the claim which cannot be supported by the disclosure of 060, 872; at the earliest, the instant claims have an effective filing date of parent application 09/500,135 filed on 2/28/00.

If not falling within the rubric of the "enzymes" now recited in claim 7, streptokinase may be reasonably considered as falling within the rubric of "factors", since streptokinase can serve as an initiating factor or agent of thrombolysis. The amendment of claim 7 has thus not overcome.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Barstad et al(5,268,454) for reasons of record.

Barstad et al teach analogs of a polypeptide immunogen which retains B-cell epitopes but which lacks T-cell epitopes. The latter are eliminated by chemical derivitization or are partially or completely deleted from the sequence. Applicant is referred to col.3, lines 55-66 and col.4, lines 61-68.

Barstad et al teach that the polypeptide may be thyroglobulin^u (col.4, line 13), which falls under the rubric of "hormones", : see stedman's medical Dictionary indicating its use as a "thyroid hormone" at page 1452. The amendment has thus not overcome.

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Applicant has urged that Barstad et al's teachings are not applicable because the instant claims refer to "a variant of a polypeptide of interest comprising a T-cell epitope". While Barstad et al show a polypeptide that has no T-cell epitopes. The examiner finds this argument unconvincing because the phrase "comprising a T-cell of interest" is considered to describe the "polypeptide of interest" before it has been altered by substitutions, deletions, etc. Nothing in the disclosure of applicant negates the elimination of all T-cell epitopes, and nothing requires the presence of a T-cell epitope in the claimed variant.

Applicant's arguments filed on 4/7/03 are unconvincing.

Newly cited prior art is utilized in the rejection stated infra. This can be stated due to the amendment, which has altered the effective filing date of the claims.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Estell (WO 99/53078, of record on form 1449).

Estell teaches subtilisins (i.e. enzymes) that have modified T-cell epitopes with a lowered immunogenicity.

Citation is proper since the instant inventive entity differs from WO 99/ 53078.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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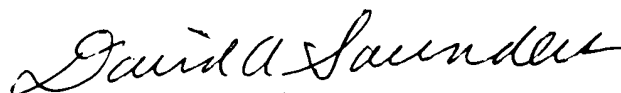
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday 8 am - 5:30 pm, ^{and on} Alternative Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-3973 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Saunders/tgd
June 18, 2003


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644